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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,649	01/03/2001	Eugene de Juan JR.	55535 (1699)	1507
21874	7590	05/28/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			JEFFERY, JOHN A	
		ART UNIT	PAPER NUMBER	
		3742		

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati	Applicant(s)
	09/756,649	DE JUAN ET AL.
Examiner	Art Unit	
John A. Jeffery	3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Periodic Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 March 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 61-108 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 108 is/are allowed.

6) Claim(s) 61-107 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 21 October 2002 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date .

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-68, 70-74, 76, 79, 80, 85, 88, 89, 94, 97, 99-101, and 103-106 are rejected under 35 USC 102(b) as being anticipated by SU733670. SU733670 discloses a surgical instrument for use in cornea removal surgery comprising a strain gauge that detects changes in pressure from the underlying tissue during use. The detected pressure from the strain gauge is used as a control signal to change the audible tone or sound volume thereby providing audible feedback to the surgeon during use.

According to the English language translation of SU '670, changes in the pressure exerted by the blade on the tissue are dynamically indicated by an associated proportional change in tone of the sound. Therefore, by monitoring such changes in pitch while cutting, the physician obtains real-time information regarding the changes in (1) tissue density, (2) tissue resistance, and (3) depth of the cut.

With regard to claim 80, while a power source is not expressly stated in the reference text, a power source is implicit in the disclosure because the instrument obtains an electrical transducer signal, amplifies it, and subsequently transforms the

amplified signal to an acoustic signal. Such electrical processes necessarily require a source of electrical power.

Joint Inventors--Common Ownership Presumed

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 75, 81-84, 90-92, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of EP349443. The claims differ from the

previously cited prior art in calling for a piezopolymer element to generate an electric signal proportional to the degree of flexion. While SU '670 discloses a rigid surgical instrument, the use of surgical cutting instruments with flexible tips is conventional and well known in the art as evidenced by EP349443 noting the flexible tip which also includes a sensor which detects the degree of flexion of the tip so that the forces exerted on the tip are measured and the incision is guided more accurately. See Abstract, particularly the "USE/ADVANTAGE" section. Also, a flexible tip would enable the instrument to be introduced in difficult-to-reach areas internally. In view of EP349443, it would have been obvious to one of ordinary skill in the art to provide a flexible tip with flexion detection means in conjunction with the previously described apparatus so that an instrument was provided that could reach difficult-to-reach internal areas via a flexible tip yet still provide a measure of the forces applied to the flexible tip during cutting.

With regard to claim 75, while SU '670 does not expressly state the means for producing the audible signal, the examiner takes Official Notice that the use of electro-acoustic devices to generate sound from an electrical signal such as speakers, earphones, and the like are well known in the art and does not constitute a patentably distinguishable feature of the invention. With regard to claims 81 and 82, the use of battery power sources is conventional and well known in the art in view of a battery's ability to provide a self-contained power source precluding the need to access mains power. The use of a connecting cable is conventional and well known in the art in

order to provide an insulated power source electrical connection to improve safety and facilitate prompt and easy replacement of the power source.

With regard to claims 90-92 and 98, the use of modular, disposable, and reusable surgical instrument tips is well known in the art so that replacement tips can be easily installed on the device as well as having the ability to reuse a replaced tip thereby lowering costs and reducing waste.

Claims 69 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of the article by Tanimoto et al entitled "Micro Force Sensor for Intravascular Neurosurgery and *In Vivo* Experiment" ("the Tanimoto article"). The claims differ from the previously cited prior art in calling for the device to be used in neurosurgical applications. The use of devices with force-sensing capability in neurosurgical applications is conventional and well known in the art as evidenced by the Tanimoto article which teaches using a micro-force sensor for surgical tools in neurological applications so that the delicate neurological regions are detected during surgery thereby minimizing damage and obtaining information about certain neurological disorders such as aneurysms. In view of the Tanimoto article, it would have been obvious to one of ordinary skill in the art to use a force-sensing tool of the previously described apparatus for neurosurgical applications so that the delicate neurological regions are detected during surgery thereby minimizing damage and obtaining information about certain neurological disorders such as aneurysms.

Claims 77, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Brown et al (US4841987). The claims differ from the previously cited prior art in calling for a microprocessor with the ability to adjust sensitivity and threshold of operation. Providing a microprocessor to process the electrical input from a force sensor in a surgical tool is conventional and well known in the art as evidenced by Brown et al (US4841987) noting microprocessors 309, 325, and 321 in Fig. 3. Moreover, potentiometers 306, 310 enable sensitivity adjustment. In view of Brown et al (US4841987), it would have been obvious to one of ordinary skill in the art to provide a microprocessor in conjunction with the previously described apparatus so that an integrated processing means was provided with low power consumption and light weight thereby reducing the number of apparatus parts and drain on the power source.

Claims 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Hall (US5411511). The claims differ from the previously cited prior art in calling for the device to comprise a shaft and a handle wherein the sensor is placed between the shaft and the handle. Providing a force sensor between a shaft and a handle on a surgical cutting apparatus for eye surgery is conventional and well known in the art as evidenced by Hall (US5411511) noting Figs. 7 and 8 wherein sensor 30 is placed between shaft (lower portion of 25 in Fig. 7) and the "handle" 35. According to col. 6, lines 4-25, by mounting the sensor in this fashion, the amount of pressure applied to the knife by the surgeon's fingers proportional to the resistance the cornea exerts on

the blade is accurately detected. In view of Hall (US5411511), it would have been obvious to one of ordinary skill in the art to so mount the sensor of the previously described apparatus so that the amount of pressure applied to the knife by the surgeon's fingers proportional to the resistance the cornea exerts on the blade is accurately detected.

Claim 93 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Shan (US5728044). The claims differ from the previously cited prior art in calling for sensing impedance or flux. However, providing strain gages to sense a change in electrical impedance responsive to flexion of a surgical tool is conventional and well known in the art as evidenced by Shan (US5728044) noting col. 6, lines 27-35 where an array of strain gages senses a change in electrical impedance to determine the degree of bending of a surgical tool. In view of Shan (US5728044), it would have been obvious to one of ordinary skill in the art to sense impedance in conjunction with the previously described apparatus so that an electrical parameter was used as the force sensing control signal thereby facilitating straightforward processing of the signal via microprocessors and other computing equipment.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Aristides (US5928158). The claim differs from the previously cited prior art in calling for the transducer to be attached to a grip portion of the device. Attaching speakers to the grips of surgical tools is conventional and well known in the

art as evidenced by Aristides (US5928158) noting speaker 15A in Fig. 1A which emits a sound warning the surgeon when nerves are contacted. Disposing the speaker in the grip housing precludes the need to have a separate speaker housing thus reducing the number of apparatus parts. In view of Aristides (US5928158), it would have been obvious to one of ordinary skill in the art to dispose the speaker of the previously described apparatus in the grip thereby precluding the need to have a separate speaker housing thus reducing the number of apparatus parts.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Epstein (US5437657). The claim differs from the previously cited prior art in calling for the transducer to be attached to the medical practitioner using the device. Providing an electromechanical transducer attached to the surgeon so that audible signals are directed solely to the practitioner is conventional and well known in the art as evidenced by Epstein (US5437657) noting headphones 250 which are worn by the surgeon while using the surgical instrument during eye surgery so that an audible warning is heard by the surgeon when the correct depth is achieved. The use of headphones ensures that the surgeon can hear the warning by blocking out ambient and background noise. In view of Epstein (US5437657), it would have been obvious to one of ordinary skill in the art to attach the transducer to the surgeon during use in order to ensure that the surgeon can hear the audible warning by blocking out ambient and background noise.

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU733670 in view of Steinberg et al (US5746748). The claims differ from the previously cited prior art in calling for a sterile kit containing the device. Providing surgical cutting implements in sterile kit form is conventional and well known in the art as evidenced by Steinberg et al (US5746748) noting Figs. 9, 10 wherein a sterile kit houses the surgical implements so that a convenient, sterile, prepackaged unit was provided which precludes the need to prepare, clean, and resterilize the instruments prior to use. See col. 8, lines 43-62. In view of Steinberg et al (US5746748), it would have been obvious to one of ordinary skill in the art to provide a sterile kit including the device of the previously described apparatus so that a convenient, sterile, prepackaged unit was provided which precludes the need to prepare, clean, and resterilize the instruments prior to use.

Allowable Subject Matter

Claim 108 is allowable over the art of record.

Response to Arguments

Applicant's arguments filed 3/1/04 have been considered but are not deemed to be persuasive. Applicant argues that although SU '670 discloses detecting static forces imparted on the surgical instrument, it does not teach or suggest detecting dynamic forces. Remarks, P. 9-10.

1. The Scope and Breadth of the Claim 1 Did Not Preclude SU '670.

The sheer breadth of the term "dynamic forces," however, does not preclude the citation of SU '670. As noted in the rejection, the SU reference teaches detecting both static and dynamic forces. Specifically, the SU reference teaches that changes in the pressure exerted by the blade on the tissue are dynamically indicated by an associated proportional change in tone of the sound. Translation of SU '670, P. 3. Moreover, according to the translation:

The control of the pressure of the tissue, which being operated upon [sic] the cutting edge of the blade provides an opportunity to obtain information about the change of the density, depth of the cut and resistance of the tissue, which being operated, in accordance with the change of the tone of the sound, which information provides an opportunity for the carrying out of delicate operations, e.g., removal of cornea without a lesion or destruction of the tissue, located underneath.

Translation of SU '670, at 3-4 (emphasis added).

Therefore, by monitoring such changes in pitch while cutting, the physician obtains real-time information regarding the changes in (1) tissue density, (2) tissue resistance, and (3) depth of the cut. See *id.*

Turning to the claims, claim 1 merely recites "detecting dynamic and static forces" imparted on the device. Moreover, in the preceding paragraph of the translation, SU '670 notes that

Under the action of the pressure of the tissue, which is being operated upon by the cutting edge of the blade, a change of the volt-ampere characteristic of the...strain gauge diode takes place, whose changes...[are] subsequently transformed and recorded...in the form of changes...in tone or sound volume.

Id. at 3 (emphasis added).

The examiner respectfully submits that SU 670's continuous detection of changes in tissue pressure on the instrument during delicate procedures, such as cornea removal surgery, and the continuous feedback of such force changes to the user via associated changes in tone pitch or volume fully meets the limitation of claim 1 merely reciting "detecting dynamic and static forces" imparted on the device.

2. SU '670 Employs a Commensurate Detector as that Used in the Invention and is Capable of Detecting Dynamic and Static Forces.

Moreover, the detector used in the instant invention to detect both static and dynamic forces is commensurate with that used in SU '670. According to the instant specification, P. 11, line 30 - P. 12, line 10, applicant states:

...[P]referred embodiments may include devices wherein the sensor element is comprised of strain gauges...contained within or attached to the shaft of the device, wherein the sensors are capable of dynamic and/or static forces applied to the device....[N]eurosurgical devices may likely better [sic] suited through use of piezoresistive materials or strain gauges, in order to convey not only dynamic forces such as texture and impact, but also static forces such as force of retraction.

Applicant's specification, at 11-12 (emphasis added).

As applicant notes, because strain gauges are capable of detecting both dynamic and static forces applied to the instrument, such detectors are contemplated as suitable for the invention. Turning to SU '670, the reference expressly states that a strain guage diode 4 is used. See the English translation, P. 3, first, third, and fourth paragraphs,

and the language of claims 1 and 2 on P. 4. Therefore, because the instant invention contemplates the use of a strain guage to detect both static and dynamic forces, and SU '670 employs such a detector, for this reason alone, the reference fully meets claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (703) 306-4601. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans, can be reached on (703) 305-5766. All faxes should be sent to the centralized fax number at (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



JOHN A. JEFFERY
PRIMARY EXAMINER

5/27/04